Appendix J

FEB 15 2007

510(k) Summary

Submitter:	NeoMetrics, Inc. 14800 28th Ave. N., Suite 150 Plymouth, MN 55447
Contact Person:	Gene Champeau President 763-559-4440 (voice) 763-559-7676 (fax)
Date Prepared:	January 12, 2007
Trade Name:	VascuPuncture™ PICC Guidewire
Classification Name and Number:	Wire, Guide, Catheter: 21 CFR 870.1330
Product Code:	DQX
Predicate Device Name and 510(k) Number	VascuPuncture PICC Guidewire, K031652, K040786, K043398
Device Description:	DEVICE DESCRIPTION The VascuPuncture™ PICC Guidewires are guidewires constructed of stainless steel and nickel titanium alloy with or without lubricious coatings. Devices are available in diameters of 0.014 to 0.018 inches and in lengths ranging from 40 to 145 cm. with a variety of coil material options available.
Intended Use:	The VascuPuncture PICC Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger Technique. The device is not intended for use in the coronary or cerebral vasculature.
Statement of Technological Comparison	Functional and performance characteristics are demonstrated through equivalence with the predicate device and testing of representative device samples as part of Design Verification Testing. Comparison is summarized in Table 1 below: Biocompatibility is demonstrated through successful completion of Biocompatibility Testing in accordance with ISO 10993 Shelf Life is demonstrated through successful completion of accelerated aging studies and subsequent testing in accordance with ISO 11070
Conclusion:	VascuPuncture™ PICC Guidewire with additional coatings and coil material are safe and equivalent to the predicate product. This conclusion is based upon the fact that this device is substantially equivalent to the predicate devices in terms of functional design, indications for use, principles of operation, risk analysis, and performance characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 16 2007

NeoMetrics, Inc.
c/o Mr. Gene Champeau
President
14800 28th Avenue, N. Suite 150
Plymouth, MN 55447

Re: K070150
VascuPuncture™ PICC Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (Two)
Product Code: DQX
Dated: January 12, 2007
Received: January 16, 2007

Dear Mr. Champeau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

B Zuckerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K070150

Device Name: **VascuPuncture™ PICC Guidewire**

Indications for Use:

The VascuPuncture PICC Guidewire is indicated for percutaneous entry of peripheral vessels using the Seldinger Technique. The device is not intended for use in the coronary or cerebral vasculature.

Prescription Use __X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K070150

(Posted November 13, 2003)